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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,025	08/29/2000	Philip J. Larkin		6639
7590	10/04/2004		EXAMINER	
Audley A Ciamporcer Jr One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003			KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
				1638

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/600,025	LARKIN ET AL.
	Examiner	Art Unit
	David H Kruse	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 January 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 and 30-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-19,33,34 and 44-46 is/are rejected.
- 7) Claim(s) 30-32 and 35-43 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 09 June 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>Same</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Continued Examination Under 37 CFR § 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 21 January 2004 has been entered.

Status of the Application

2. This Office action is in response to Applicant's amendments and remarks filed 21 January 2004.
3. The Objection to the Oath/Declaration is withdrawn in view of Applicant's amendment to the Specification.
4. The drawings were received on 9 June 2003. These drawings are acceptable to the Examiner.
5. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments to the claims.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

7. Claims 30 and 45 objected to because of the following informalities: At claim 30, line 6, the phrase “for culturing the plant medium” is redundant and should be deleted. See also claim 45, line 5. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. Claims 1-19, 33 and 34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims all depend upon independent claim 1. Claim 1 is indefinite because at line 6, the limitation “a desired pH level” is indefinite and relative, and does not teach the metes and bounds of the claimed invention. On page 4 of the specification, Applicant only teaches that a pH of between 5.5 and 6.5 is most preferable, but does not teach what the metes and bounds of a “desired” pH level encompasses, as it appears to be relative to the plant material being cultured. Claims 2-9 and 11-19 are also indefinite because they do not obviate the indefiniteness of claim 1.

At claims 7 and 33, the limitation “derived” renders the claims indefinite because it is unclear how the material is “derived” or what manipulative steps are involved. Deletion of this limitation is suggested to obviate this rejection.

At claims 8 and 34, the limitations “any culture which gives rise to somatic embryos, any culture which gives rise to shoots and plant tissues” renders the claims indefinite because it is unclear what the metes and bounds of these limitations are.

At claim 10, the limitation "the pH is maintained" lacks proper antecedent basis in claim 2.

9. Claims 1-9 and 11-19 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for methods of transforming a *Papaver* sp. of poppy using a culture medium whose pH has been buffered to stabilize the pH at 5.5-6.5, does not reasonably provide enablement for said method for transforming any poppy species wherein the pH is buffered at a "desired" pH level. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 5 March 2003. Applicant's arguments filed 21 January 2004 have been fully considered but they are not persuasive. This rejection has been modified from that of a previous Office action.

Applicant argues that the cited reference (Hanson *et al* 1999) provides no evidence that a skilled practitioner would be unable to transform a variety of poppy plant species using conventional methods of plant transformation and regeneration with the addition of the novel steps of the present invention, i.e., the addition of a buffering agent to prevent, reduce, or delay the rise in pH of the plant material or culture medium.

Applicant argues that methods of the invention are based on the use of conventional methods of plant transformation and regeneration techniques but include the additional step of stabilizing the pH of the medium, and that the previous Office Action provides no reason to believe that a skilled practitioner would be unable to use conventional

methods such as those described in the Park *et al.* article with the methods of the present invention to transform an alkaloid producing poppy plant (page 11 of the Remarks). These arguments are not found to be persuasive. Park *et al* only teach a method of transformation that is standard in the art, and it is unclear how this supports Applicant's arguments for enablement. The instant claims have been found to be indefinite for the reasons given *supra*. It would have required undue trial and error experimentation by one of skill in the art to have to determine the "desired pH level" for each and every poppy species as broadly claimed in order to practice the claimed method within the full scope of the invention. Applicant has only provided guidance on how to practice the claimed method for the poppy species *Papaver somniferum* by stabilizing the culture media within the pH range of 5.5-6.5. Hanson *et al* (1999) teaches that one of skill in the art must determine by empiric experimentation what conditions are optimal for a method of transformation and regeneration for each species of plant, adapting methods known in the art as the starting point.

Claim Rejections - 35 USC § 102

10. Claims 1-9, 11-13, 16 and 17 remain rejected and claims 44-46 are rejected under 35 U.S.C. § 102(b) as being anticipated by Yoshimatsu *et al* 1996 (pages 243-252 in Biotechnology in Agriculture and Forestry Vol. 38, Plant Protoplasts and Genetic Engineering VII (ed. by Y.P.S. Bajaj), Springer-Verlag, Berlin) taken with the evidence of Wetherell 1982 (Introduction to In Vitro Propagation, Avery Publishing Group Inc. Wayne, New Jersey, pages 27, 40 and 46). This rejection has been modified to include art that teaches the inherent property of the teachings of Yoshimatsu *et al*. This

rejection is repeated for the reason of record as set forth in the last Office action mailed 5 March 2003. Applicant's arguments filed 21 January 2004 have been fully considered but they are not persuasive.

Applicant argues that Yoshimatsu et al. 1996, fails to disclose or suggest the method steps of the present invention (page 11, last paragraph of the Remarks). Applicant argues that claims 1-9, 11-13, 16 and 17 require that the transformation of alkaloid producing poppy plant material and/or the culturing of the transformed plants material occur in the presence of a buffering agent that prevents, reduces the rate of or delays the rise in pH of the plant material or culture medium from a desired pH level (page 12 of the Remarks). Applicant argues that it is not enough that a buffering agent be present, the buffering agent must be able to prevent, reduce the rate of or delay the rise in pH of the plant material or culture medium, and that Yoshimatsu does not explicitly require that the MS or Woody Plant media be added in an amount sufficient to prevent, reduce the rate of, or delay the rise in pH of the plant material or culture medium (page 13 of the Remarks). These arguments are not found to be persuasive. The Examine has included the disclosure of Wetherell (1992) that teaches the inherent properties of the disclosure of Yoshimatsu et al 91996). Wetherell discloses that the optimal initial pH value is between 5.0 and 6.0, and that phosphates in culture medium play a role in resisting pH shifts (pages 27 and 40). Wetherell discloses the composition of MS medium comprising ammonium nitrate, potassium nitrate and potassium dihydrogen phosphate (page 46). The MS medium used by Yoshimatsu would inherently meet the limitations of reducing the rate of or delaying a rise in pH given the

disclosure of Wetherell. See *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC SCalf 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then the prior art anticipates the claimed method.

Claim Rejections - 35 USC § 103

11. Claims 14 and 15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshimatsu *et al* 1996 (pages 243-252 in Biotechnology in Agriculture and Forestry Vol. 38, Plant Protoplasts and Genetic Engineering VII (ed. by Y.P.S. Bajaj), Springer-Verlag, Berlin) in view of Bidney (U.S. Patent 5,932,782). This rejection is repeated for the reason of record as set forth in the last Office action mailed 5 March 2003. Applicant's arguments filed 21 January 2004 have been fully considered but they are not persuasive.

Applicant's arguments as directed to Yoshimatsu have been addressed supra.

The teaches of Bidney are directed to a method of plant transformation that was well known in the art at the time of Applicant's invention, which one of ordinary skill in the art at the time of the invention would have considered functionally equivalent to the *Agrobacterium* transformation method taught by Applicant in the examples.

Conclusion

12. 1-19, 33, 34 and 44-46 are rejected.
13. Claims 30, 31, 32 and 35-43 are objected to.
14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.



DAVID H. KRUSE, PH.D.
PATENT EXAMINER

David H. Kruse, Ph.D.
30 September 2004

16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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